

The Drawings

The attached replacement sheets of drawings includes changes to Fig. 1-6b and replaces the original sheets including Fig. 1-6b. The replacement drawings are formal. No substantive changes have been made, therefore, no marked up versions are enclosed.

REMARKS

In reply to the Office Action of March 19, 2008, Applicants submit the following remarks. Claims 1, 6, 8, 12 and 14 have been amended. Support for the amendment to claim 1 can be found at least in claim 13 as previously pending. Claims 6 and 14 have been amended to change "suture" to "suturing". Claims 8 and 12 have been amended to change "handle" to "handle assembly". Claim 13 is canceled. Claim 25 is new and is support at least by the application as filed in FIG. 5 and the corresponding text. Applicant respectfully requests reconsideration in view of the foregoing amendment and these remarks.

Drawings

Formal drawings have been prepared and accompany this response. No substantive changes have been made to the figures other than formalization.

Section 112 Rejections

Claims 8-9 and 12-13 were rejected under 35 U.S.C. § 112, para. 2 as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claims 8 and 12 have been amended to read "handle assembly" instead of "handle". In light of these amendments, applicants submit that the claims are clear and definite, and request withdrawal of the rejection under 35 U.S.C. § 112, para. 2.

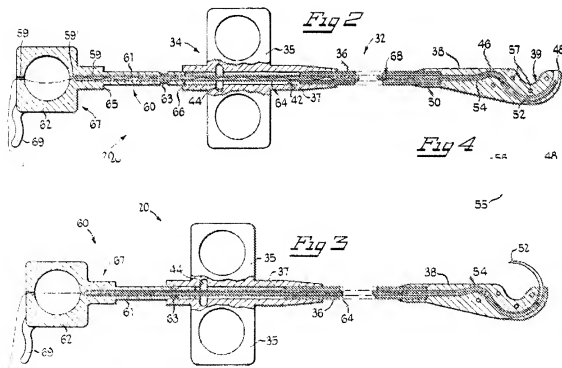
Section 103 Rejections

Claims 1-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,741,276 ("Poloyko") in view of U.S. Patent No. 5,254,130 ("Poncet") and in some cases, further in view of U.S. Patent No. 6,315,784 ("Djurovic"). The applicants respectfully disagree in light of the amendments made to claim 1.

Amended claim 1 is directed to surgical suture placement device with a handle assembly, an elongated hollow outer tube connected at a proximal end to the handle assembly, a suturing

assembly rotatably secured to a distal end of the elongated hollow outer tube, and a hollow inner tube located within the hollow outer tube and connecting the handle assembly to the suturing assembly by traversing the inside of the elongated hollow outer tube. Rotating the handle assembly concurrently rotates the hollow inner tube and the suture assembly as a unit.

Poloyko describes an instrument that has a plunger 62 that is connected to a tube 64 (col. 6, lines 32-43, FIG. 2). The tube 64 is within tube 36 (col. 5, lines 34-56). Tube 36 is affixed to head 38, such as with glue. Head 38 encloses a needle 52 and flexible rod 54 (col. 6, lines 44-67). The flexible rod 54 is affixed to the end of flexible rod 54. The rod must be fairly flexible, that is flexible enough to straighten and bend around a series of curves, as shown in FIGS. 2 and 3 (see in particular where item numbers 46 and 52 are pointed out in FIG. 2). FIGS. 2 and 3 are reproduced below for the Examiner's convenience.



The Examiner notes that Poloyko does not teach that the suture assembly is rotatably secured to the outer tube. For this limitation, the Examiner turns to Poncet for a device that has a distal portion 11 that can be rotated about its own axis. The Examiner argues that it would have

been obvious to one of ordinary skill in the art to modify the apparatus of Poloyko by providing the suture assembly (i.e., head 38) such that it is rotatably secured to the outer tube. However, amended claim 1 requires that rotating the handle assembly concurrently rotates the hollow inner tube and suture assembly as a unit. Poloyko's plunger 62 is not described as being rotatable with respect to the outer tube 36. Even if the plunger 62 were rotatable, rotating Poloyko's plunger 62 would cause tube 64 to rotate. Rotating the tube 64 would torque flexible rod 54 and the flexibility of the rod 54 would cause the rod 54 to twist within head 38. Thus, rotating the plunger 62 would not cause head 38 to rotate with the tube 64 *as a unit*.

Stiffening rod 54 to ensure that rotating the rod 54 would cause the head 38 and tube 64 to rotate as a unit would disable Poloyko's device from operating in the way intended. That is, the plunger would no longer be able to push the needle out of the head 38 if the rod 54 were stiff and could not bend in the curved needle cavity. Such a modification cannot be made to Poloyko's device, because the proposed modification cannot change the principle of operation of the device (MPEP 2143.01 VI).

Djurovic was relied upon to show an alternative to feed suturing material to the needle and does not teach this feature.

In light of the amendment made to claim 1, applicant submits that there is no *prima facie* case of obviousness. Claims 2-12 and new claim 25 depend from claim 1, and thus for at least the same reason, there is no *prima facie* case of obviousness made for these claims. Therefore, Applicants request withdrawal of the rejection under 35 U.S.C. §103.

In light of the amendments and arguments made herein, Applicants respectfully request allowance of the pending claims, including the method claims, which can be rejoined upon allowance of the device claims.

Applicant : Beane et al.
Serial No. : 10/613,502
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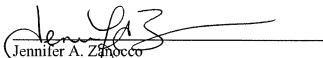
Attorney's Docket No.: 07917-0160001 / UMMC 02-09

The three-month extension of time fee in the amount of \$525 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing attorney docket 07917-0160001.

Respectfully submitted,

Date:

Sept 18, 2008


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